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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Cerami *et al.*

Application No.: 10/017,457

Group Art Unit: 3736

Filed: December 7, 2001

Examiner: To be assigned

For: IMMUNE MODULATION DEVICE  
FOR USE IN ANIMALS Attorney Docket No.: 10162-006-999

LETTER

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

We are in receipt of a Letter (a copy of which is attached as Exhibit A) that allegedly was filed in the U.S. Patent and Trademark Office on June 27, 2002, by Mr. Woodrow ("Woodrow Letter") of Johnson & Johnson ("J&J") in connection with the above-captioned application. This Letter is submitted to set the record straight and to correct the inaccuracies in the Woodrow Letter.

The relevant facts are as follows. VLN/LLC ("VLN") assignee of the above-identified application, and Ortho-Biotech Inc<sup>1</sup>, and The R.W. Johnson Research Institute, a division of Ortho-McNeil Pharmaceuticals, Inc., assignee of a co-pending application directed to the same subject matter, entered into an Exclusive License Agreement ("Agreement") effective as of June 1, 1999, for VLN's virtual lymph node technology, which was the subject of a previously filed patent application and related know-how. Research, performed by both parties, was undertaken pursuant to the Agreement. On or about May 10, 2001, and pursuant to the Agreement, Mr. Woodrow provided to counsel for applicants a copy of a patent application entitled "Immune Modulation Device for Use in Animals" ("Ortho Application"), filed in the USPTO on May 11, 2001 as a provisional application. Mr. Woodrow's transmittal letter stated that the Ortho Application embodied a new design for a virtual lymph node developed by Ortho. As for inventorship on such application, Mr. Woodrow concluded that he had no basis to believe that Anthony Cerami or Carla Cerami of VLN ("Ceramis") had provided any inventive contribution, and consequently, the Ortho application named only Kevor TenHuisen, Ilya Koyfman and Joel Rosenblatt of Ortho ("Ortho inventors") as inventors.

<sup>1</sup> Based on correspondence received from counsel for the Ortho inventors, Johnson & Johnson appears to be the real party in interest.

We reviewed the Ortho application and investigated the facts available to us to ascertain what role, if any, VLN scientists may have had in making the invention described and claimed in such application. We concluded that the Ceramis and Qiao-Wen Xie (VLN Inventors), based on their contributions, were co-inventors and consequently, should be named as such on the Ortho Application. Mr. Woodrow was advised that based on information available to us, the VLN Inventors should be named as co-inventors in the Ortho Application. Mr. Woodrow requested documentation supporting the VLN Inventors' contribution for his independent review. In response, we repeatedly urged that the contributions of all individuals who worked on the project resulting in the Ortho Application be evaluated to ensure the correctness of the inventor entity. An exchange of documents and/or a meeting with all relevant individuals was suggested. Mr. Woodrow has persistently and steadfastly refused to either meet, exchange documents, or provide any information supporting the inventive contribution of the Ortho inventors. The exchanges between counsel for the VLN and Ortho inventors were by telephone and letters. Copies of the letters are attached as Exhibit B.

As is immediately apparent, Mr. Woodrow's conclusions as to inventorship are necessarily and deliberately incomplete. In light of the requirement that those claiming inventorship must timely, explicitly and tenaciously assert their inventorship, we filed the above-identified application to preserve the rights of all the correct inventors. Under the Agreement mentioned above, inventions jointly owned by VLN and Ortho are controlled by VLN.

Pending resolution of the inventorship dispute, we respectfully intend to pursue prosecution of the subject application.

For the sake of completeness and accuracy of the record, we respectfully request that a copy of this Letter and the attachments be placed in the file of this and the co-pending Ortho Application.

Respectfully submitted,

Date August 29, 2002

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